

SALK1520-2 (088802-8752)  
09/042,488**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: Evans et al.	Group Art Unit: 1633
Application No.: 09/042,488	Examiner: S. Kaushal
Filing Date: March 16, 1998	Applicant's Representative: Stephen E. Reiter
For: METHOD FOR MODULATING EXPRESSION OF EXOGENOUS GENES IN MAMMALIAN SYSTEMS, AND PRODUCTS RELATED THERE TO	

**Agenda for Personal Interview on November 21, 2002****Discuss rejections under 35 USC § 112, first paragraph, in Office Action mailed 08/13/2002****I. Possession of the claimed invention**

- discuss grouping of claims
- discuss teachings of the disclosure beyond that of the working examples
- discuss how the specification describes all features required by the present claims
  - in particular: (i) the ecdysone response elements (and modifications thereof)
  - (ii) the modified ecdysone receptor (and all components thereof, i.e., a ligand binding domain capable of binding an ecdysteroid; a DNA-binding domain, and an activation domain)

**II. Enablement**

- discuss support for all of the required elements of the claims as identified above
- discuss disclosure being commensurate with the scope of the claims
- discuss knowledge of one of skill in the art in applying the teachings provided
- discuss routine experimentation required, e.g., to create the required DNA constructs, and to introduce them into cells in the presence of ligands to modulate expression of the target gene

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**CLAIM SUMMARY FOR SALK1520-2**

**Methods of gene regulation in isolated cells** (Claims 1, 3-9, 11-13, 15-24, 39, 40, 47-55, 57-69, 70, and 71)

Claims 1, 3-9, 11-13, 15-21, 39, 40, 47-49, 50-55, 57-66, 70, and 71 (independent in bold)  
– methods for modulating the expression of an exogenous gene in an isolated cell

Claims 22, 23, 67, and 68  
– methods of inducing the expression of an exogenous gene in an isolated cell

Claims 24 and 69  
– methods for the expression of a recombinant product detrimental to isolated host cells

**Methods of gene regulation in a mammalian subject** (Claims 72-77)

Claims 72 and 75  
– methods for modulating the expression of an exogenous gene in a mammalian subject

Claims 73, 74, 76 and 77  
– methods of inducing the expression of an exogenous gene in a mammalian subject

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Components of the isolated cell (support in specification identified in parenthesis)

Independent claims	exogenous gene component	modified ecdysone receptor component
1, 23, 24	gene under control of response element to which the modified ecdysone receptor binds (p. 32, l. 33 through p. 33, l. 34)	LBD for ecdysteroid (p.12, l. 32 through p. 13, l. 11) DBD from DNA-binding protein (p. 13, l. 13 through p. 18, l. 16) activation domain of a transcription factor (p. 18, l. 18 through p. 19, l. 4)
22	gene under control of response element to which the modified ecdysone receptor binds (p. 32, l. 33 through p. 33, l. 34)	receptor under control of an <u>inducible</u> promoter (p. 37, l. 19-31) LBD for ecdysteroid (p.12, l. 32 through p. 13, l. 11) DBD from DNA-binding protein (p. 13, l. 13 through p. 18, l. 16) activation domain of a transcription factor (p. 18, l. 18 through p. 19, l. 4)
50, 68, 69	gene under the control of an <u>ecdysone</u> response element (p. 32, l. 7-31)	LBD for ecdysteroid (p.12, l. 32 through p. 13, l. 11) DBD from DNA-binding protein (p. 13, l. 13 through p. 18, l. 16) activation domain of a transcription factor (p. 18, l. 18 through p. 19, l. 4) substantially no binding affinity for endogenous response elements (p. 16, l. 35 through p. 17, l. 12)
67	gene under the control of an <u>ecdysone</u> response element (p. 32, l. 7-31)	receptor under control of an <u>inducible</u> promoter (p. 37, l. 19-31) LBD for ecdysteroid (p.12, l. 32 through p. 13, l. 11) DBD from DNA-binding protein (p. 13, l. 13 through p. 18, l. 16) activation domain of a transcription factor (p. 18, l. 18 through p. 19, l. 4) substantially no binding affinity for endogenous response elements(p. 16, l. 35 through p. 17, l. 12)
70	gene under the control of an <u>ecdysone</u> response element (p. 32, l. 7-31)	LBD for ecdysteroid (p.12, l. 32 through p. 13, l. 11) DBD from DNA-binding protein (p. 13, l. 13 through p. 18, l. 16) activation domain of a transcription factor (p. 18, l. 18 through p. 19, l. 4) substantially no constitutive activity in mammalian cells (p. 12, l. 27-30) (p. 16, l. 35 through p. 17, l. 12)
71	gene under the control of an <u>ecdysone</u> response element (p. 32, l. 7-31)	LBD for ecdysteroid (p.12, l. 32 through p. 13, l. 11) DBD from DNA-binding protein (p. 13, l. 13 through p. 18, l. 16) activation domain of a transcription factor (p. 18, l. 18 through p. 19, l. 4) altered DNA binding specificity relative to wildtype (p. 8, l. 16-21)